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Jennewine

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(54) **INTEGRATED ANALYTE SENSOR AND INFUSION DEVICE AND METHODS THEREFOR**

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(52) **U.S. Cl.**

CPC ***A61B 5/1473*** (2013.01); ***A61B 5/14532*** (2013.01); ***A61M 5/14248*** (2013.01); *A61B 5/14503* (2013.01); *A61M 2005/14252* (2013.01); *A61M 2005/1726* (2013.01); *A61M 2205/3569* (2013.01); *A61M 2205/3592* (2013.01); *A61M 2230/20* (2013.01); *A61M 2230/201* (2013.01)

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CPC A61M 2230/20; A61M 2005/14252; A61M 2005/3592; A61M 2005/1726; A61M 5/14248; A61M 2205/3569; A61M 2230/201; A61B 5/145; A61B 5/14503; A61B 5/14532; A61B 4/1468; A61B 5/1473; A61B 5/1486; A61B 5/14865

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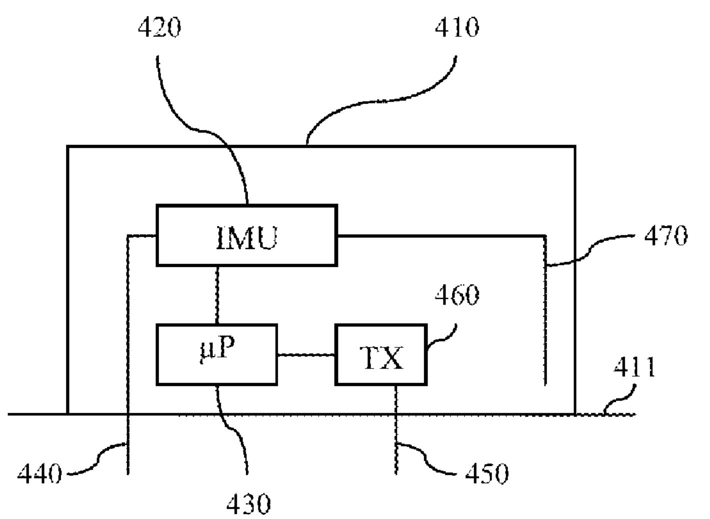
(57) **ABSTRACT**

Method and system for providing an integrated analyte monitoring system and on-body patch pump with multiple cannulas and a sensor combination is provided.

27 Claims, 3 Drawing Sheets



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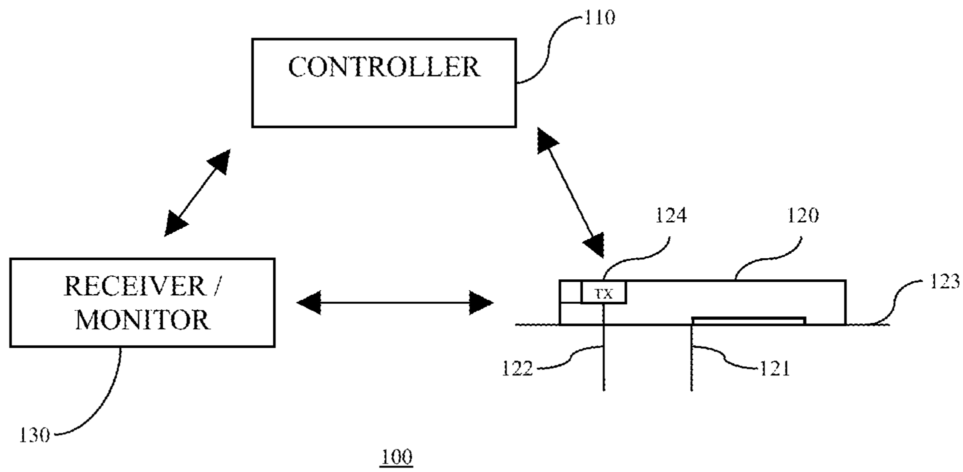

FIGURE 1

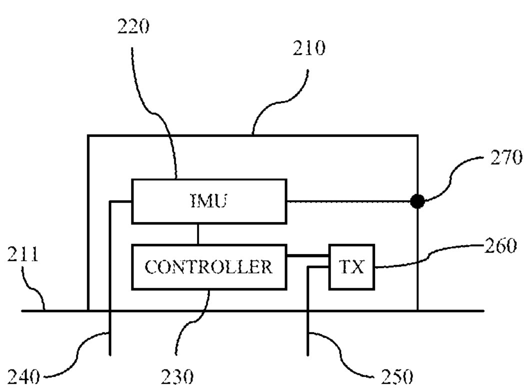

FIGURE 2A

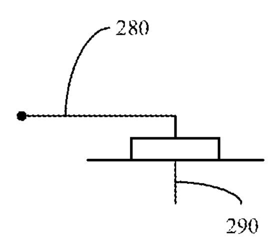

FIGURE 2B

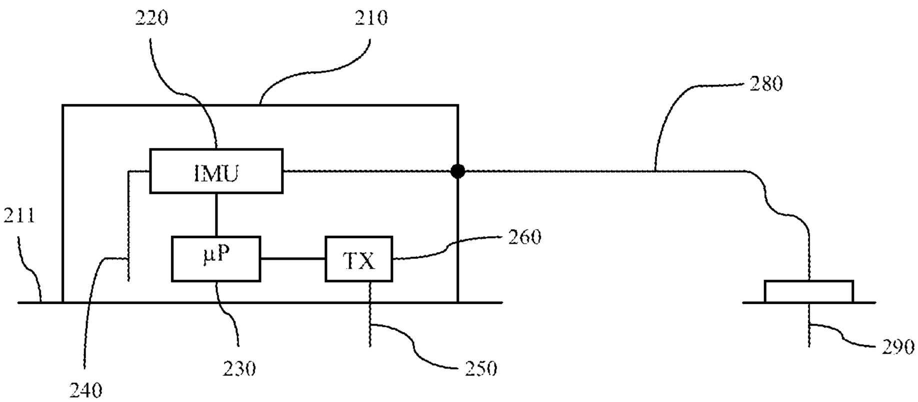

FIGURE 3

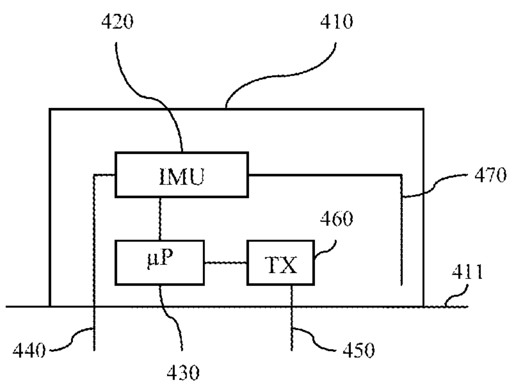

FIGURE 4A

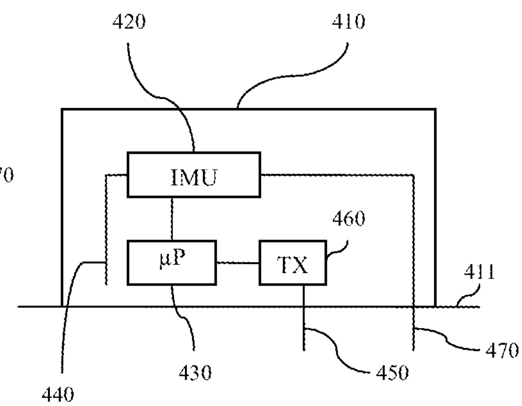

FIGURE 4B

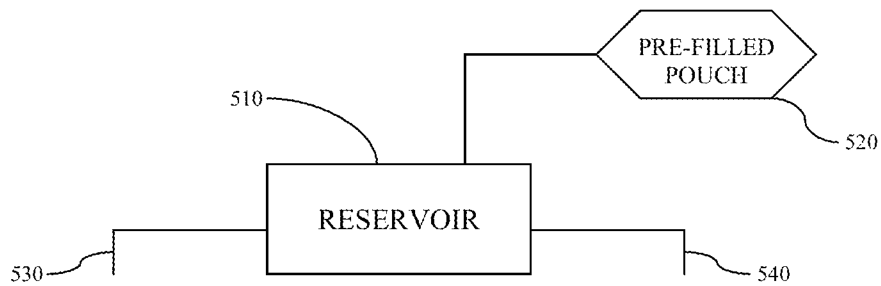

FIGURE 5A

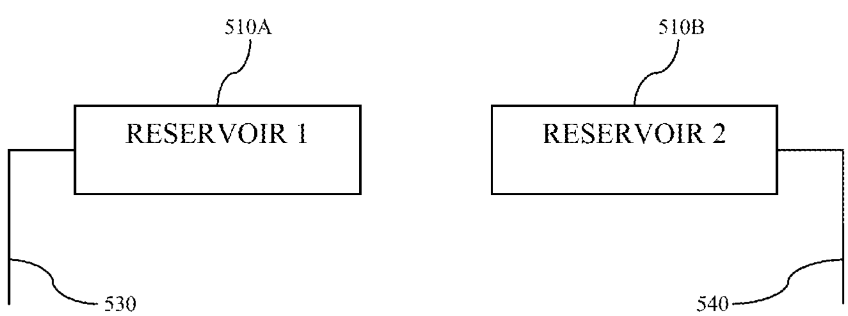

FIGURE 5B

INTEGRATED ANALYTE SENSOR AND INFUSION DEVICE AND METHODS THEREFOR

BACKGROUND

Diabetic patients periodically administer insulin to sustain their physiological conditions. Typically, these patients administer doses of either fast acting or slow acting insulin using needle type syringes, for example, prior to meals, and/or at a suitable time during the course of each day contemporaneously with the blood glucose level testing using fingerstick testing, for example. If insulin is not suitably administered, the diabetic patients risk serious if not fatal damage to the body.

Continued development and improvement in the external infusion pump therapy in recent years have drawn much appeal to the diabetic patients for, among others, improved management of diabetes by better regulating and controlling the intake of insulin. Typically, the patient inserts a cannula which is connected to as infusion tubing attached to an external pump, and insulin is administered based on preprogrammed basal profiles. Moreover, the external infusion devices presently available include computational capability to determined suitable bolus doses such as carbohydrate bolus and correction bolus, for example, to be administered in conjunction with the infusion device executing the patient's basal profile.

Typically, the infusion site where the cannula is positioned under the skin layer of the patient experiences results in tissue or skin trauma. Thus, the infusion site is typically changed with each change of the infusion set, for example, every three days or so. Furthermore, the infusion site may also be prone to infection and other adverse consequences as a result of the transcutaneous placement of the cannula for insulin delivery.

In addition, current development in analyte monitoring typically uses a transcutaneously positioned biosensor which is in fluid contact with the patient's analyte to monitor, for example, analyte levels of the patient. Given that the useful life of the biosensor may not coincide with the typical 3 or so day usage of an infusion set, a patient using an infusion device and also using an analyte monitoring system must periodically replace the cannula for the infusion system, and the biosensor for the analyte monitoring system, and which may be at different times during the course of infusion therapy and analyte monitoring.

SUMMARY OF THE INVENTION

In view of the foregoing, in accordance with the various embodiments of the present invention, there is provided an integrated analyte monitoring system and on-body patch pump with multiple cannulas and a sensor combination. In particular, within the scope of the present invention, there are provided methods and system for deploying multiple infusion cannulas for use with an extended analyte sensor (for example, a 7 day sensor).

These and other objects, features and advantages of the present invention will become more fully apparent from the following detailed description of the embodiments, the appended claims and the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a block diagram illustrating an overall therapy management system for practicing one embodiment of the present invention;

FIGS. **2**A and **2**B illustrate multiple cannulas integrated with an extended use analyte sensor in a patch pump configuration in accordance with one embodiment of the present invention;

FIG. **3** illustrates a combined patch pump system integrated with the second cannula during the second part of the sensor life in accordance with one embodiment of the present invention;

FIGS. **4**A and **4**B illustrate multiple cannulas integrated with an extended use analyte sensor in a patch pump configuration in accordance with another embodiment of the present invention; and

FIGS. **5**A and **5**B illustrate alternate embodiments showing infusion fluid provision in accordance with one embodiment of the present invention.

DETAILED DESCRIPTION

As described below, within the scope of the present invention, there are provided methods and systems for integrating therapeutic fluid infusion cannula for use with an on-body patch pump and an analyte sensor configured for continuous monitoring of a patient's analyte. In particular, within the scope of the present invention, there is provided an integrated multiple infusion cannulas with analyte sensors for continuous monitoring and infusion for approximately seven days of continuous use.

FIG. **1** is a block diagram illustrating an overall therapy management system for practicing one embodiment of the present invention. Referring to FIG. **1**, the therapy management system **100** includes a controller **110** configured for bidirectional wireless communication with an on-body patch pump **120**. In one embodiment, the controller **110** is configured to control the operation of the patch pump **120** based on, for example, preprogrammed delivery profiles for infusion of therapeutic agent, such as, including but not limited to insulin. In one aspect, the controller **110** includes one or more user input unit, and one or more user output unit for user directed programming of the patch pump **120** using the controller **110**, and further, to provide visual, auditory, and/or vibratory output signals for communicating with the user.

Referring back to FIG. **1**, the patch pump **120** in one embodiment is provided with an adhesive layer **123** which is configured to adhere on the skin of a patient during use. The patch pump **120** includes a cannula **121** for establishing a fluid path between a reservoir (not shown) containing the therapeutic fluid for delivery and the infusion site of the patient. Also shown in the Figure is a sensor **122**. As shown in FIG. **1**, a portion of the cannula **121** and the sensor **122** are positioned under the skin of the patient, and thus, at least a portion of each are configured to extend from the lower surface of the patch pump **120** through the skin layer of the patient.

In one embodiment, the sensor **122** includes an analyte sensor which is configured to establish fluid contact with the interstitial fluid of the patient so as to detect the analyte level, such as glucose level, of the patient. That is, the transmitter unit **124** may be configured to receive one or more signals from the analyte sensor **122** corresponding to the detected analyte levels of the patient, and to transmit the information corresponding to the detected analyte levels to the receiver/monitor **130** and/or the controller **120**. In particular, over a communication link such as an RF wireless communication link, the transmitter unit **124** may be configured to transmit data associated with the detected analyte levels periodically, and/or intermittently and repeatedly to one or more other devices such as controller **110** and/or the receiver/monitor **130** for further data processing and analysis.

Referring back to FIG. **1**, in one embodiment, the one or more of the controller **110** and the receiver/monitor **130** may include a strip port configured to receive a test strip for capillary blood glucose testing. In one aspect, the glucose level measured using the test strip may in addition, be configured to provide periodic calibration of the sensor **122** to assure and improve the accuracy of the analyte levels detected by the analyte sensor **122**.

Referring again to FIG. **1**, the analyte sensor **122** may include, but not limited to short term subcutaneous analyte sensors or transdermal analyte sensors, for example, which are configured to detect analyte levels of a patient over a predetermined time period, and after which, a replacement of the sensors is necessary. Additional analytes that may be monitored, determined or detected the analyte monitoring system **110** include, for example, acetyl choline, amylase, amyln, bilirubin, cholesterol, chorionic gonadotropin, creatine kinase (e.g., CK-MB), creatine, DNA, fructosamine, glucose, glutamine, growth hormones, hormones, ketones, lactate, measures for oxidative stress (such as 8-iso PGF2gamma), peroxide, prostate-specific antigen, prothrombin, RNA, thyroid stimulating hormone, and troponin. The concentration of drugs, such as, for example, antibiotics (e.g., gentamicin, vancomycin, and the like), biguanides, digitoxin, digoxin, drugs of abuse, GLP-1, insulin, PPAR agonists, sulfonylureas, theophylline, thiazolidinediones, and warfarin, may also be determined.

Referring yet again to FIG. **1**, both the cannula **121** and the sensor **122** may be transcutaneously positioned under the skin layer of the patient using an insertion device (not shown) that includes a sharp penetrating member such as an insertion needle. Alternatively, the sensor **122** and the cannula **121** may be configured with sufficient rigidity to pierce through the skin of the patient without additional piercing guides such as the sharp penetrating member of the insertion device.

Further, the transmitter unit **124** in one embodiment is configured to maintain electrical communication with the sensor **122** such that the detected analyte levels from the sensor **122** may be transmitted by the transmitter unit **124** to the controller **110**. In this manner, the controller **110** may be configured to communicate with the transmitter unit **124** so as to provide analyte monitoring functions.

Alternatively or in addition to the controller **110**, there may be provided a receiver/monitor unit **130** which is configured to communicate with the transmitter unit **124** to receive the detected analyte levels for further processing. In one aspect, the patch pump **120** control functions and the analyte monitoring functions may be incorporated in the controller **110** such that the patient need only carry one device. In addition, the receiver/monitor unit **130** in one embodiment may include for example, a desktop computer terminal, a data communication enabled kiosk, a laptop computer, a handheld computing device such as a personal digital assistant (PDAs), or a data communication enabled mobile telephone.

Similar to the controller **110** discussed above, the receiver/monitor unit **130** may include a user interface unit which may include a display unit and/or an audio output unit such as, for example, a speaker, and/or any other suitable user interface mechanism for displaying or informing the user of such devices.

In one embodiment, both the controller **110** and the receive/monitor **130** are configured with a substantially compact housing and sized such that the devices may be easily and comfortably be held in the patient's hand, worn on the patient's clothing, or placed inside a pocket of the patient's clothing without much discomfort. In addition, the patch pump **120** may be configured with a substantially compact housing and sized such that the patient experiences minimal discomfort during the seven or more days of continuous on-body use.

FIGS. **2**A and **2**B illustrate multiple cannulas integrated with an extended use analyte sensor in a patch pump configuration in accordance with one embodiment of the present invention. Referring to FIG. **2**A, patch pump **210** in one embodiment includes a controller **230** (e.g., a microprocessor) operatively coupled to an infusion management unit (IMU) **220** which includes, among others, a reservoir (not shown) for retaining therapeutic agent such as insulin for delivery to the patient. Within the scope of the present invention, the infusion management unit (IMU) **220** may include other components such as power supply (e.g., battery), and/or fluid path management section which, in one embodiment, may be configured to connect the a cannula **240** to the reservoir for therapeutic agent delivery to the patient, and further, to control the placement or positioning of the first cannula **240**, and subsequent retraction of the first cannula **240** upon reaching the end of its useful life cycle.

Moreover, in one embodiment, the infusion management unit (IMU) **220** may include a transceiver (not shown) for bidirectional communication with one or more of the controller **110** and the receiver/monitor **130**. In one embodiment, the transceiver may be configured to receive infusion related commands or instruction from the one or more of the controller **110** and the receiver/monitor **130**, and further, to transmit one or more information associated with the fluid flow information or the operating condition of the patch pump **120**.

Referring back to FIG. **2**A, the infusion management unit (IMU) **220** in one embodiment is connected to a port **270** provided substantially at the housing of the patch pump **210**. In one aspect, the infusion management unit (IMU) **220** is configured to maintain a fluid path to the port **270**. In one embodiment, the port **270** may include a self-sealing septum which is substantially configured to be water proof. In accordance with an alternate embodiment, the port **270** may include a uni-directional connector for mating with an infusion tubing **280** to establish fluid path between the infusion management unit **220** and a second cannula **290** as shown in FIG. **2**B. That is, in one embodiment, the infusion management unit (IMU) **270** may be configured to manage the infusion of the therapeutic agent such that the first cannula **240** transcutaneously positioned at the first infusion site is used for a predetermined time period (for example, approximately three to four days), and thereafter, retract the first cannula **240** from the first infusion site (and retained within the housing of the patch pump **210**), while connecting the infusion tubing **280** to the port **270** establishes a fluid path to the second cannula **290** to infuse the therapeutic agent to the patient in a continuous manner.

Referring yet again to FIG. **2**A, also provided in the patch pump **210** is a sensor **250** such as, for example, an analyte sensor, at least a portion of which is transcutaneously positioned under the skin layer of the patient. As shown, the sensor **250** is operatively coupled to a transmitter unit **260** which is configured to communicate with, for example, the controller **110** (FIG. **1**) and/or the receiver/monitor **130** (FIG. **1**). In one aspect, the sensor **250** is configured for approximately seven or more days of use. As such, it is desirable to change the infusion site of the therapeutic agent delivery at approximately mid point in the usage life of the sensor **250** (i.e., after approximately three or four days of use).

Accordingly, in accordance with one embodiment of the present invention, the first cannula **240** is configured for transcutaneous delivery of the therapeutic agent at the first infusion site for the initial time period of approximately three or four days. Thereafter, the first cannula **240** is retracted from the infusion site under the control and operation of one or more of the controller **230** and the infusion management unit **220**, and in one embodiment, wholly retained within the housing of the patch pump **210**. Prior to the retraction of the first cannula **240**, the infusion tubing **280** connected to the second cannula **290** is coupled to the port **270** to establish fluid contact with the infusion management unit (IMU) **220**. This is shown in FIG. **3**.

The tubing **280** may be either pre-primed or is primed by the controller **230** and/or the infusion management unit (IMU) **220**. In addition, the tip of the tubing **280** for mating or connection to the port **270** may be configured to engage with the port **270** so as to establish a water tight seal. Further, the second cannula **290** is transcutaneously positioned at the second infusion site (which is different from the first infusion site on the patient) for delivery of the therapeutic agent.

In one embodiment, the insertion process of the second cannula **290** may be automated using an insertion device such as an insertion gun that is configured to couple to the second cannula **290** (for example, the insertion needle coupled to the second cannula **290**) and which includes a spring bias driven insertion mechanism. Alternatively, the insertion process may be primarily manual whereby the patient manually inserts the second cannula at the desired second infusion site.

In this manner, in one embodiment, the patch pump **210** may be configured for operation for approximately seven or more days for therapeutic agent delivery, and further, integrated with a continuous monitoring system wherein the sensor **250** is configured to continuously monitor the analyte level of the patient during the seven or more days of use without interruption. The monitored analyte levels as well as the therapeutic agent delivery associated information are communicated to the controller **110** (FIG. **1**) and/or the receiver/monitor **130** by, for example, the transmitter unit **260**. Furthermore, by changing the infusion site for the therapeutic agent delivery to the patient, potential for skin irritation and/or damage to patient's tissue at the infusion site by the cannula and/or the therapeutic agent may be minimized.

FIGS. **4**A and **4**B illustrate multiple cannulas integrated with an extended use analyte sensor in a patch pump configuration in accordance with another embodiment of the present invention. Referring to FIG. **4**A, patch pump **410** in one embodiment includes a first cannula **440** and a second cannula **470** disposed therein. Also shown in the Figure is the infusion management unit (IMU) **420** which is operatively coupled to the first cannula **440** and the second cannula **470**.

Further, a controller **430** is operatively coupled to the infusion management unit (IMU) **420** and to a transmitter unit **460**. Similar to the controller **230** discussed above in conjunction with FIGS. **2**A-**2**B and **3**, the controller **430** in one embodiment is configured to control the operating functions of the infusion management unit (IMU) **420** and the transmitter unit **450**, for managing therapeutic agent delivery via the respective first and second cannulas **440**, **470**, and for managing the data transmission of the transmitter unit **460** that is configured to receive one or more analyte associated signals from a sensor **450**.

Referring back to FIG. **4**A, in one embodiment, the initial transcutaneous placement of the sensor **450** and the first cannula **440** is performed substantially simultaneously (or near simultaneously). Thereafter, when a predetermined time period has lapsed, the first cannula **450** is configured to be withdrawn from the infusion site, while the second cannula (pre-deployed) is transcutaneously inserted into the patient. An adhesive patch **411** is configured to substantially fixedly retain the patch pump **410** on the adhered portion of the patient's skin during the entire duration of the patch pump **410** usage (for example, seven or more days).

Referring now to FIG. **4**B, it can be seen that the first cannula **440** in one embodiment is withdrawn from the first infusion site, and substantially and entirely retained within the housing of the patch pump **410**, while the second cannula **470** is transcutaneously positioned at the second infusion site. As discussed above, the infusion management unit (IMU) **420** in one embodiment includes a reservoir containing the therapeutic agent, and to establish the appropriate fluid communication with the first and second cannulas **440**, **470**. Optionally, the controller **430** may be configured to control the operation of the infusion management unit (IMU) **420** so as to provide continuous and uninterrupted delivery of the therapeutic agent to the patient during the duration in which the sensor **450** is detecting the analyte levels of the patient.

In one embodiment, the controller **110** (FIG. **1**) and/or the receiver/monitor **130** may be configured to substantially control the programming of the patch pump **410** such that the operation of the infusion management unit (IMU) **420** and the controller **430** of the patch pump **410** are configured to receive the commands or instructions from the controller **110** and/or the receiver/monitor **130** to execute the appropriate functions. Examples of such functions include, but are not limited to the delivery of programmed basal profiles, delivery of carbohydrate bolus dosage, implementing a temporary basal modification, insertion and/or retraction of the first cannula **440**, and the insertion and/or retraction of the second cannula **470**.

In a further embodiment, a mounting base (not shown) may be provided which includes the adhesive layer **411** there under, and which may be configured to guide the insertion of the first cannula **440** and the sensor **450**. Further, the first cannula **440** and the sensor **450** may be transcutaneously positioned prior to the placement or positioning of the patch pump **410** on the patient's skin. In this configuration, the first cannula **440** and the sensor **450** may not be initially retained within the housing of the patch pump **410**. Rather, an insertion device may be used to separately insert the first cannula **440** and the sensor **450**. Thereafter, the patch pump **410** may be configured to couple to the transcutaneously positioned first cannula **440** and the sensor **450** such that the first cannula establishes fluid contact with the infusion management unit (IMU) **420**, and the sensor **450** is in electrical contact with the transmitter unit **460**.

FIGS. **5**A and **5**B illustrate alternate embodiments showing infusion fluid provision in accordance with one embodiment of the present invention. Referring to FIG. **5**A, it can be seen that a first cannula **530** and a second cannula **540** are coupled to the reservoir **510**, while the reservoir **510** is further coupled to a pre-filled pouch **520**. In one embodiment, the infusion management unit (IMU) **210** or **420** may be configured to include the first and second cannulas **530**, **540**, the reservoir **510** and the pre-filled pouch **520**. The pre-filled pouch is configured to hold therapeutic agent such as insulin to replenish the reservoir during the usage life of the patch pump **210**, **410**.

Referring now to FIG. **5**B, it can be seen that the first cannula **430** is coupled to a first reservoir **510**A, while the second cannula **540** is coupled to a second reservoir **510**B. Again, the infusion management unit (IMU) **210** or **420** may be configured to include the first and second cannulas **530**, **540**, each respectively coupled to the first and second reservoirs **510**A, **510**B.

Referring back to the Figures, while not shown, the patch pump **210**, **410** within the scope of the present invention may include additional components that are configured to assist and/or improve the therapeutic agent delivery and analyte monitoring. Such additional components may include, but are not limited to, one or more power supplies such as batteries, one or more user input units (e.g., mechanical and/or electro-mechanical, button, switch, and the like), one or more user output units (e.g., a visual indicator, an audible alert, a vibratory alert, or a combination thereof), one or more additional redundant microprocessors to protect from failure modes of the patch pump **210**, **410**, or a leakage sensor for detecting any leakage of the therapeutic agent or any other fluid within the housing of the patch pump **210**, **410** that may damage the internal components.

Accordingly, an integrated therapy management system in one embodiment includes a first cannula for transcutaneous placement under a skin layer of a patient at a first infusion site for a first time period, a second cannula for transcutaneous placement under the skin layer of the patient at a second infusion site for a second time period, and an analyte sensor configured for fluid contact with an analyte of the patient for a predetermined time period, where the first cannula and the second cannula are configured to deliver a therapeutic agent to the patient during the predetermined time period.

There may be also provided a housing, where the first cannula, the second cannula and the sensor are coupled to the housing.

Further, there may be provided a housing, where the first cannula and the sensor are coupled to the housing, and further, where second cannula may be connected to the housing by an infusion tubing.

In one aspect, the first infusion site and the second infusion site may be separated by a predetermined distance.

Also, the predetermined time period may include approximately seven days.

The system may also include a reservoir coupled to the first cannula and the second cannula.

In a further aspect, there may be provided a first reservoir coupled to the first cannula, and a second reservoir coupled to the second cannula.

Moreover, when the second cannula is transcutaneously positioned, the first cannula may be withdrawn from the first infusion site.

The sensor may include an analyte sensor, and the therapeutic agent may include insulin.

A method in accordance with another embodiment includes positioning a portion of a first cannula under the skin of a patient, positioning a portion of a sensor under the skin of the patient, positioning a portion of a second cannula under the skin of a patient, and withdrawing the first cannula from the patient while retaining the sensor position under the skin of the patient.

The positioning the portion of the first cannula and the positioning the portion of the sensor may be substantially simultaneously performed.

In yet a further aspect, the sensor may be positioned under the skin of the patient for approximately seven days.

An integrated therapy management system in accordance with still another embodiment includes an on-body micropump including a first cannula for transcutaneous placement under a skin layer of a patient at a first infusion site for a first time period, a second cannula for transcutaneous placement under the skin layer of the patient at a second infusion site for a second time period, an analyte sensor configured for fluid contact with an analyte of the patient for a predetermined time period, and a controller in signal communication with the on-body micropump, the controller configured to transmit one or more signals to the micropump to control the delivery of a therapeutic agent to the patient using one or more of the first cannula and the second cannula.

The micropump may further include a transmitter unit operatively coupled to the analyte sensor.

The controller may be configured to receive one or more signals associated with one or more analyte levels of the patient from the transmitter unit.

In addition, the controller may be further configured to receive one or more signals associated with the therapeutic agent delivery.

Moreover, in yet a further aspect, the controller may be in signal communication with the on-body micropump over a wireless communication link.

A kit in yet a further embodiment includes a first cannula for transcutaneous placement under a skin layer of a patient at a first infusion site for a first time period, a second cannula for transcutaneous placement under the skin layer of the patient at a second infusion site for a second time period, and an analyte sensor configured for fluid contact with an analyte of the patient for a predetermined time period, where the first cannula and the second cannula are configured to deliver a therapeutic agent to the patient during the predetermined time period.

The kit may also include a housing, where the first cannula, the second cannula and the sensor are coupled to the housing.

Moreover, the kit may include a housing, where the first cannula and the sensor are coupled to the housing, and further, where second cannula may be connected to the housing by an infusion tubing.

In a further aspect, the kit may include a reservoir coupled to the first cannula and the second cannula, or alternatively, the kit may include a first reservoir coupled to the first cannula, and a second reservoir coupled to the second cannula.

Various other modifications and alterations in the structure and method of operation of this invention will be apparent to those skilled in the art without departing from the scope and spirit of the invention. Although the invention has been described in connection with specific preferred embodiments, it should be understood that the invention as claimed should not be unduly limited to such specific embodiments. It is intended that the following claims define the scope of the present invention and that structures and methods within the scope of these claims and their equivalents be covered thereby.

What is claimed is:

1. An integrated therapy management system, comprising:

a housing including a bottom surface for placement on a skin layer;

a reservoir including a therapeutic agent provided within the housing;

a first cannula for transcutaneous placement under the skin layer of a patient at a first infusion site for a first time period, the first cannula connected to the reservoir at a first position on the reservoir;

a second cannula for transcutaneous placement under the skin layer of the patient at a second infusion site for a second time period, the second cannula connected to the reservoir at a second position on the reservoir, the second position on the reservoir different from the first position on the reservoir; and

a sensor configured for fluid contact with an analyte of the patient for a predetermined time period, the sensor having at least a portion coupled to the housing;

wherein the first cannula and the second cannula are configured to deliver the therapeutic agent to the patient during the predetermined time period; and

wherein at least a portion of the first cannula is configured to extend from the bottom surface of the housing at a first location and at least a portion of the sensor is configured to extend from the bottom surface of the housing at a second location when the housing is placed on the skin surface.

2. The system of claim **1** wherein the second cannula is connected to the housing by an infusion tubing.

3. The system of claim **1** wherein the first infusion site and the second infusion site are separated by a predetermined distance.

4. The system of claim **1** wherein the predetermined time period includes approximately seven days.

5. The system of claim **1** wherein the reservoir includes a first reservoir including the first position coupled to the first cannula, and a second reservoir including the second position coupled to the second cannula.

6. The system of claim **1** wherein when the second cannula is transcutaneously positioned, the first cannula is withdrawn from the first infusion site.

7. The system of claim **1** wherein the sensor includes an analyte sensor.

8. The system of claim **1** wherein the therapeutic agent includes insulin.

9. The system of claim **1** wherein the housing includes a port disposed thereon, the port configured for fluid communication with the reservoir in the housing.

10. The system of claim **9** wherein the port is coupled to the second position on the reservoir for fluid communication with the second cannula.

11. The system of claim **1** wherein the first cannula is entirely retained within the housing during the second time period.

12. The system of claim **1** wherein at least a portion of the second cannula is configured to extend from the bottom surface of the housing at a third location when the housing is placed on the skin surface.

13. The system of claim **1** wherein the first location and the second location on the bottom surface of the housing are spaced apart from each other.

14. An integrated therapy management system, comprising:

an on-body micropump including:

a pump housing including a reservoir for retaining a therapeutic agent, the housing including a bottom surface for placement on a skin layer;

a first cannula for transcutaneous placement under the skin layer of a patient at a first infusion site for a first time period, wherein at least a portion of the first cannula is configured to extend from the bottom surface of the pump housing at a first location on the housing when the housing is placed on the skin surface, and wherein the first cannula is connected to the reservoir at a first location on the reservoir;

a second cannula for transcutaneous placement under the skin layer of the patient at a second infusion site for a second time period, the second cannula coupled to the pump housing and connected to the reservoir at a second location on the reservoir; and

an analyte sensor configured for fluid contact with an analyte of the patient for a predetermined time period, the analyte sensor having at least a portion configured to extend from the bottom surface of the pump housing at a second location when the housing is placed on the skin surface; and

a controller in signal communication with the on-body micropump, the controller configured to transmit one or more signals to the micropump to control the delivery of the therapeutic agent from the reservoir to the patient using one or more of the first cannula and the second cannula.

15. The system of claim **14** wherein the micropump further includes a transmitter unit operatively coupled to the analyte sensor.

16. The system of claim **15** wherein the controller is configured to receive one or more signals associated with one or more analyte levels of the patient from the transmitter unit.

17. The system of claim **16** wherein the controller is further configured to receive one or more signals associated with the therapeutic agent delivery.

18. The system of claim **14** wherein the controller is in signal communication with the on-body micropump over a wireless communication link.

19. An integrated therapy management system, comprising:

a patch pump including:

a compact housing including a bottom surface for placement on a skin layer;

a reservoir provided in the compact housing;

a first cannula for transcutaneous placement under the skin layer of a patient at a first infusion site for a first time period to deliver a medication from the reservoir in the housing, the first cannula coupled to a first location on the reservoir;

a second cannula for transcutaneous placement under the skin layer of the patient at a second infusion site for a second time period to deliver the medication from the reservoir in the housing, the second cannula coupled to a second location on the reservoir; and

an analyte sensor in fluid contact with an analyte of the patient for a predetermined time period, the analyte sensor configured to monitor the analyte level of the patient, at least a portion of the analyte sensor operatively coupled to the compact housing;

wherein the first time period and the second time period are substantially nonoverlapping, and further the combined first and second time periods substantially correspond to the predetermined time period during which the analyte sensor is in fluid contact with the analyte of the patient; and

wherein at least a portion of the first cannula is configured to extend from the bottom surface of the housing at a first location and at least a portion of the analyte sensor is configured to extend from the bottom surface of the housing at a second location when the housing is placed on the skin surface.

20. The system of claim **19** wherein the analyte sensor is a glucose sensor.

21. The system of claim **19** including an infusion tubing connected to the compact housing, wherein the second cannula is connected to the infusion tubing.

22. The system of claim **19** including a controller provided in the housing and operatively coupled to the analyte sensor to process one or more signals received from the analyte sensor.

23. The system of claim **19** wherein the second cannula extends from the housing at a third location.

24. The system of claim **23** wherein the third location is not on the bottom surface of the housing.

25. An integrated therapy management system, comprising:

a fluid reservoir;

a first cannula for transcutaneous placement under a skin layer of a patient at a first infusion site for a first time period, the first cannula connected to the fluid reservoir at a first location on the fluid reservoir;

a second cannula for transcutaneous placement under the skin layer of the patient at a second infusion site for a second time period, the second cannula connected to the fluid reservoir at a second location on the fluid reservoir;

an analyte sensor configured for fluid contact with an analyte of the patient for a predetermined time period;

a housing having a bottom surface configured for contacting the skin surface, wherein at least a portion of the first cannula is configured to extend from the bottom surface of the housing at a first location and at least a portion of the analyte sensor is configured to extend from the bottom surface of the housing at a second location when the housing is placed on the skin surface; and

a control unit operatively coupled to the first cannula, the second cannula and the analyte sensor, the control unit configured to control, at least in part, the delivery of a therapeutic agent from the fluid reservoir via the first cannula and the second cannula, and further, to process one or more analyte related signals from the analyte sensor;

wherein the therapeutic agent is delivered via the first cannula during the first time period, and further, via the second cannula during the second time period;

wherein the sum of the first time period and the second time period substantially corresponds to the predetermined time period during which the analyte sensor is in fluid contact with the analyte; and further wherein the therapeutic agent is delivered substantially continuously during the predetermined time period during which the analyte sensor is in fluid contact with the analyte.

26. The system of claim **25** wherein the second cannula extends from the housing at a third location.

27. The system of claim **26** wherein the third location is not on the bottom surface of the housing.

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